Commonwealth of Virginia Department of Health
Advance Health Care Directives Registry

A. Format for Submissions at Conceptual Stage (Part 1)

Proposals at the conceptual stage must contain information in the following areas: (1) qualifications and experience, (2) project characteristics, (3) project financing, and (4) such additional information as may seem prudent which is not inconsistent with the requirements of the PPEA. Suggestions for presenting information to be included in proposals at the Conceptual Stage include:

1. Qualification and Experience

a. Identify the legal structure of the firm or consortium of firms making the proposal. Identify the organizational structure for the project, the management approach and how each partner and major subcontractor ($1 million or more) in the structure fits into the overall team. All members of the offeror's team, including major subcontractors known to the proposer must be identified at the time a proposal is submitted for the Conceptual Stage

The National Living Will Registry, Inc. is a privately held New Jersey corporation doing business as the U.S. Living Will Registry®. Joseph T. Barmakian, MD is the founder and CEO, and oversees operations and new projects. The proposed project would be completed in-house without the need for outside contractors or subcontractors. In the same way that the Vermont, Washington and Nevada Advance Directive Registries were launched, our staff will work with Department of Health staff to customize a Registry for Virginia according to the requirements of the statute and the regulations promulgated by the department.

Founded in 1996, the U.S. Living Will Registry® has developed and currently operates a secure, web based system and administrative infrastructure to electronically store advance directives, organ donor information, emergency contact information, and make this information available to health care providers across the country 24 hours a day through an automated system. Our policies and procedures were developed in consultation with health care providers, lawyers and law makers to ensure all health care providers have access to the documents and information, while maintaining privacy and confidentiality.

The Registry provides an easy and cost-effective way for states to establish custom advance directive and organ donor registries. The Registry's sophisticated system allows for all health care providers, or certain types of health care providers to access all documents registered from a particular state.

The Registry solution has evolved throughout thirteen years of operations and currently consists of:

- a secure web based software application / database
- a highly available hosting infrastructure with best in class application continuity process
- an acclaimed community outreach program and content
- a comprehensive operational infrastructure supporting
    - document scanning
    - handling directive updates
    - contacting every registrant annually for updates
    - supporting registrants' access from organizations
    - partner and technical support

b. Describe the experience of the firm or consortium of firms making the proposal and the key principals involved in the proposed project including experience with projects of comparable size and complexity. Describe the length of time in business, business experience, public sector experience and other engagements of the firm or consortium of firms.

The organization's experience:

Managing a statewide healthcare declarations registry

The U.S. Living will Registry® has been providing national registry service for more than thirteen years working directly with health care providers and community partners. The Registry also has specific experience in developing and launching state-sponsored Advance Directive and Organ Donor Registries. Over the past six years, the states of Vermont, Washington and Nevada have selected the U.S Living Will Registry® to develop, launch and operate their state Advance Directive Registries. These successfully implemented and currently operational projects can be viewed on-line by visiting the respective web sites, listed in Exhibit 3. In each instance, the Registry's existing framework was utilized to quickly and easily create customized web screens, enrollment letters, Registrant ID cards, stationary and envelopes branded with the state's specific look and feel and state logo. The state sites link into our secure, time-tested database powered by proprietary and patent protected software, and housed in a Level 3 data center with layers of electrical power and Internet protections and redundancies. The U.S. Living Will Registry® is currently in discussions with a number of other states looking for a turn-key health care directive and organ donor registry.

Staffing Qualifications

Joseph T. Barmakian, MD is the founder and president of the U.S. Living Will Registry®. Dr. Barmakian is a board certified orthopaedic surgeon who recognized the need for a national, centralized repository for advance directives and organ donor information in 1996. Over the past 13 years, he has worked with hospital attorneys, administrators, nurses, social workers, religious leaders and hospital chaplains, ethics committees, organ donor procurement organizations, community organizations, doctors, Legislators, computer software designers and equipment consultants, and members of the public, to create a reliable, secure and flexible system to store these important documents electronically and to make them available to health care providers whenever and wherever they are needed. The current system has been thoroughly tested, and with sophisticated custom software, is now easily adaptable to run state sponsored registries, as well as serve as a comprehensive document management system for large hospital networks. Dr. Barmakian oversees the operations of the Registry, and makes the strategic decisions necessary to keep up with advances in technology as well as developments in the medical, ethical and societal aspects of end-of-life care.

Dave Levenson has been in charge of writing software and managing the equipment at the U.S. Living Will Registry® for 13 years. Dave's background with AT&T and as a consultant to Bell Labs were invaluable in the initial implementation of a computer/telephone system. As the system has grown and morphed over the years to a web based system, his talents as a software writer, programmer and system designer allowed the Registry to keep step with rapidly advancing technologies. His experience with the banking industry's computer systems has helped to make the Registry safe and secure, and maintain the integrity and confidentiality of the database.

Joan Civile has been with the Registry for six years. She manages the day-to-day operations of the office and monitors and maintains quality control, communicates with registrants, health care providers and clients, and manages the data entry operations and staff. Joan holds a degree in Gerontology and has experience with the elderly population from previous employment at a senior housing facility. This background in gerontology makes her uniquely suited to help deal with the questions and problems frequently encountered with elderly registrants.

Katie Urban has been with the Registry for the past four years. Her work in Support & Client Services is invaluable in making the important transition from written contract to working system. Katie holds a teaching certificate and taught in the classroom for two years prior to joining the Registry staff. Her teaching background is a perfect fit for her role as manager of support and client services. She is in charge of instructing new Registry client administrators and users on how to use the system for submitting and retrieving documents and for setting up passwords for users. Katie interfaces directly with clients and would be the contact person at the Registry for the proposed Virginia State Registry.

Barbara Erb has been with the Registry for almost thirteen years. Her experience and knowledge of Registry procedures, as well as her background in hospital administration, make Barbara a tremendous resource to the rest of the Registry staff. Her knowledge of HIPPA regulations and confidentiality requirements fit well in her role as the Registry's HIPPA control officer. Other duties include documentation of procedures, maintenance and updating of policies and procedures, managing invoices and billing of clients, keeping forms and letters up-to-date, and maintaining the security of documents before shredding. Barbara oversees troubleshooting operations, and helps with support of both registrants and clients.

c. Provide the names, addresses, and telephone numbers of persons within the firm or consortium of firms who may be contacted for further information.

All of the persons listed above can be reached at the U.S. Living Will Registry's offices listed below. The main contact person for this project is:

Katie Urban
808 South Avenue, West
2nd Floor
Westfield, NJ 07090

Telephone: 908-654-1441
Fax: 908-654-1919

Email: Katie@uslivingwillregistry.com

d. Provide a current or most recently audited financial statement of the firm or firms and each partner with an equity interest of twenty percent or greater.

Current financial statements for the corporation have been prepared through the end of May 2009 by the accounting firm of Israel, Kootman & Company expressly for this proposal, and are available for review in Exhibit A.

e. Provide information on the level of commitment by the firm or consortium of firms to use Department of Minority Business Enterprise certified firms in developing and implementing the project.

The Registry will be happy to work with minority firms to implement and market the Virginia Registry. We plan on doing the development work in-house without using outside contractors or subcontractors.

f. For each firm or major subcontractor that will perform construction and/or design activities, provide the following information:

(1) A sworn certification by an authorized representative of the firm attesting to the fact that the firm is not currently debarred or suspended by any federal, state or local government entity.

The sworn statement is attached in Exhibit B.

(2) A completed qualification statement on a form developed by the Commonwealth that reviews all relevant information regarding technical qualifications and capabilities, firm resources and business integrity of the firm, including but not limited to, bonding capacities, insurance coverage and firm equipment. This statement shall also include a mandatory disclosure by the firm for the past three years any of the following conduct:

We will complete the qualification form as requested. The areas listed below are addressed individually. Collectively, there is nothing to disclose in this regard.

(A) bankruptcy filings
None to disclose.

(B) liquidated damages
None to disclose.

(C) fines, assessments or penalties
None to disclose.

(D) judgments or awards in contract disputes
None to disclose.

(E) contract defaults, contract terminations
None to disclose.

(F) license revocations, suspensions, other disciplinary actions
None to disclose.

(G) prior debarments or suspensions by a governmental entity
None to disclose.

(H) denials of prequalification, findings of non-responsibility

None to disclose.

(I) safety past performance data, including fatality incidents, Experience Modification Rating, Total Recordable Injury Rate and Total Lost Workday Incidence Rate

There have been no injuries or fatalities and no lost work days due to work related injury in the history of the company.

(J) violations of any federal, state or local criminal or civil law

None to disclose.

(K) criminal indictments or investigations

None to disclose.

(L) legal claims filed by or against the firm

None to disclose.

2. Project Characteristics

a. Provide a description of the project, including the conceptual design. Describe the proposed project in sufficient detail so that type and intent of the project, the location, and the communities that may be affected are clearly identified.

The project is to develop and launch an on-line registry for the secure electronic storage and easy retrieval of advance health care directive documents, including health care power of attorney and declaration of an anatomical gift, according to 12VAC5-67-10. The Registry we propose will be a customized version of the existing, time-tested system already in place and currently in use by the states of Vermont, Washington and Nevada, and which is also being used to manage all advance directives throughout the entire Virginia based Sentara Healthcare System. The database is housed in a secure, level 3 data center and the system is powered by proprietary and patent-protected software, which has been continuously upgraded and fine-tuned over the last thirteen years. Rather than make the system overly complex with simultaneous storage of continually changing medical record information, the Registry is focused on secure and reliable storage and retrieval of advance directives and organ donor information. The registry can be easily utilized as an application on top of any electronic medical record system; accessible by a simple click on a menu item or icon to take the user to the Registry page. Therefore, there will be no problems with all hospitals and health care providers accessing documents from the registry, regardless of which, if any, electronic medical record system they have chosen to use. The system was designed to be customizable, so that some or all of the various features can be chosen to create a unique version of the existing basic framework. This flexibility allows for the accommodation of the different requirements and specifications that are often included in state statutes.

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An overview of the proposed system will be presented here.

The basic design is for documents to be submitted for registration accompanied by a Registration Agreement. The Agreement is customized to your state's needs, and usually contains the registrant's identifying information, emergency contact information, and a statement certifying that the advance directive/anatomical gift declaration was executed without undue duress, represents their wishes and authorizes release of the document to health care providers. The identifying information is entered into the database and the document scanned, creating a read-only pdf image of the document, which is linked to the registrant's information. The registrant is identified either by a randomly generated unique alpha-numeric Registration ID, or alternately, according to the state's regulations, can be identified by an existing unique identifier such as the driver's license #. A letter is then automatically generated that summarizes the new registrant's identifying information, welcomes them to the registry and contains an embedded Wallet ID card containing their Registration ID and instructions on how to access their document on-line. Labels are also embedded in the letter, that can be affixed to the driver's license and insurance card, notifying health care providers that an advance directive and/or declaration of anatomical gift document is stored in the Registry. Each year, on the anniversary of the registration, the registrant is sent an "update letter", reminding them of their registration, giving them the opportunity to update any information in their record, and asking them to certify that the document on file still reflects their wishes. New labels and a new Wallet ID card are included each year. The registrant can access their document on-line using any web browser by signing in with their Registration ID. They can view their document, print copies, and view a report that details when and who has accessed their documents. Registrants are, of course, free to share their Registration ID with their relatives, doctors and whomever they choose. If a registrant wishes to be part of the registry, but does not wish to store their actual document in the registry, they can register a "document locator form". This form lists the location of the actual document or copies, and is registered and scanned into the system just as an advance directive would be registered. It lists the location(s) of the document and copies, so that it can be easily retrieved, but maintains the registrant's complete privacy--- preventing anyone from seeing the actual contents of the document until it is retrieved.

Health care providers that have been given authorization by the state to gain access to the Registry are provided with an Organization ID # and Access Code to gain access to the system. Health care organizations administer usernames and access to the registry by their employees, so that all access to documents is tracked and traceable to a particular authorized user. Organizations such as hospitals, nursing homes, hospices, ambulatory surgery centers, organ procurement organizations, and outpatient centers are registered and can be identified and organized by class. Access to documents can be restricted according to class by the state's choice. Authorized health care providers are permitted to register documents, and can access documents using the Registrant's ID, or by searching for the full or partial last name and birth date of the registrant. In this way, authorized health care providers can access a person's documents without seeing the Wallet card. The data provided with the document include not only the registrant's identifying information and emergency contact information, but also include a notation of the date when the document and information were last updated. All transactions are logged and users identified by username, so that access to documents can be tracked and recorded.

Standard and custom reports are available to detail statistics as to how many documents are registered, how many documents are accessed—when and by whom, and various other reports to track registry usage for HIPAA compliance.

We envision access to the registry through a gateway web page that is hosted by the Virginia Department of Health. This page offers information about the registry, has forms available to download, and links through which the user gains access to the actual database, which is invisibly hosted by the U.S. Living Will Registry®. Moving from the Virginia Department of Health registry home page to a database hosted page is seamless and virtually unnoticeable. The same graphics, header and footer and style characteristics of the Department of Health portal page are maintained in the deeper pages. This seamless transition can be seen on-line by going to the Vermont, Washington and Nevada registry web pages. Please see Exhibit 4. With this system, Department of Health personnel have complete control of the home page, and can post announcements or make changes at will.

The system as described above is a basic version of the project. There are many options and features that can be added to the system without incurring any additional cost on the part of the state. Features that have been previously programmed into the system, or have been developed at the request of other clients, can be utilized by the Virginia project without additional charge.

We also offer additional services that are available for an additional charge. These include Public Service Announcements, marketing services and mail inserts.

b. Identify and fully describe any work to be performed by the public entity.

Virginia's responsibilities for the project are detailed in the Project Schedule below. Items where the "Task Owner" is listed as "VA DOH" (Virginia Department of Health), are the responsibility of the Commonwealth. These tasks mostly involve providing the graphics for the web page header/footer, preparing the home page that is hosted by the DOH, and participating in the timely preparation and prompt approval of the various forms and letters necessary for the project's completion. We will offer guidance and assistance throughout the project to help meet the scheduled launch date.

c. Identify the projected positive social, economic and environmental impacts of the project.

The positive social aspects of the project are significant and undeniable. The Florida case of Terri Schiavo, who was in a vegetative state for years and did not have an advance directive, points to the devastating social and political fallout that can result from a family's disagreement. In this case, the family members disagreed on her care, and because there was no advance directive, the state and federal courts, as well as the state and federal legislatures and even the governor of Florida and President of the United States became embroiled in a decision that should have been made by the patient. The benefits of a registry where a person's wishes can be securely stored, yet easily accessible to health care providers and family members, will keep the courts and politicians out of this private and personal area. Having an advance directive that is up to date and relatively available removes the guilt-ridden burden from family members and allows the patient to have their wishes honored.

The economic savings from the elimination of unwanted and unnecessary end of life care is a welcome by-product of an advance directive registry. In the absence of a document detailing a patient's wishes, family members often choose to tell doctors to "do whatever you can" to prolong the life of their loved one, even when there is no hope for recovery, thereby avoiding an emotional and difficult decision. This "non-decision" can result in needless suffering on the part of the patient, utilizing expensive and scarce medical resources that only temporarily prolong life.

The organ donation aspect of the registry provides another significant benefit. Knowing a person's wishes regarding organ donation has multiple positive effects. Firstly, the family will have a much easier time making a decision about organ donation if they know the wishes of the patient, and can see a document detailing those wishes and signed by their loved one. Secondly, if organ donation was the choice of the patient, the entire organ procurement process can be completed quickly and efficiently. Such speed is critical to the organ donation process. Society at large will benefit by having an up to date organ donation document readily available through a state-wide registry.

d. Identify the proposed schedule for the work on the project, including the estimated time for completion.

Project Schedule

Below is the initial high level project schedule. Nearly all of the required functionality and operational support elements needed for the project are present in the U.S. Living Will Registry's existing solution deployed on a national and statewide basis. Therefore, it is estimated the Virginia Registry can be fully operational in nine weeks.

Project Plan

Project Stage	Task and Activities	Project Week	Task Owner
KICK-OFF	Kick-off meeting	Week 1	
	Walk through existing System and Operation		USLWR
	Review Initial Customization Requirements		USLWR
	Review		USLWR
DESIGN/ CUSTOMIZE		Week 2 – 4	
	Finalize Customization Requirements		
	Look and Feel – VA State		VA-DOH/
	Forms, Letters, Cards, Enrollment Agreements		USLWR
	State Portal Page		
	Design State Portal Page		
	Build State DOH Portal Page on VA DOH site		VA – DOH
	Establish Link to Hosted Registry		VA – DOH

	Create Registry Site Customization		
	Customize for VA "wrapper" look and feel		USLWR
	Create Forms and Document Customization		
	State Forms		USLWR
	Registration Agreement		USLWR
	Enrollment Letter		USLWR
	Wallet Cards / Stickers		USLWR
	Annual Update Letter		USLWR
	Revocation Form		USLWR
	Provider Registration Form		USLWR
	Envelopes		USLWR
	Report Customization if required		USLWR
REVIEW AND TEST		Week 5 – 6	
	Review-Operational Process		
	Health care Provider/Professional Enrollment		VA – DOH/ USLWR
	Registrant Enrollment		VA – DOH/ USLWR
	Document Scanning		VA – DOH/ USLWR
	Enrollment Fulfillment		VA – DOH/ USLWR
	Annual Update Process		VA – DOH/ USLWR
	Revocation Process		VA – DOH/ USLWR
	System Test		
	User Log ON		VA – DOH/ USLWR
	Virginia State Portal & Links		USLWR
	Document Retrieval – via Registration ID Number on Wallet Card		VA – DOH/ USLWR
	Document Retrieval – via Health Care Provider System		VA – DOH/ USLWR
	Reporting		VA – DOH/ USLWR
	Provider Admin Console		VA – DOH/ USLWR
	User Acceptance Test		VA – DOH/ USLWR
PARTNER ENROLLMENT / TRAINING		Week 7 – ongoing	
	Enroll Health Care Facilities / Partners		
	Set up system access		USLWR

	Assign Provider IDs		USLWR
	Train on System Access and Access Admin		USLWR
TRAINING		Week 8	
	Train Virginia Staff		VA – DOH/ USLWR
	Train other stakeholder organizations		USLWR
LAUNCH			
	Public PR and Media Launch Event		VA – DOH
	Community Events		VA – DOH
DAY-TO-DAY REGISTRY OPERATIONS		Week 9 – Ongoing	
	Document Receipt/Scanning/Loading		USLWR
	Enrollment Kit Fulfillment		USLWR
	Annual Updates		USLWR
	Daily Registry Back-up		USLWR
	Hosting / Scheduled Maintenance		USLWR
	Document Fax Support		USLWR
	User / Registrant / Health Care Facility		USLWR
	Help Line		USLWR
	Reporting		USLWR

Deliverables

The U.S. Living Will Registry® will deliver the Commonwealth of Virginia Department of Health with a fully functional hosted Advance Directive Registry, which will satisfy all of the requirements outlined above. The specific elements of this include:

<u>Secure Hosted Application which includes:</u>

- Secure database to store secure scanned pdf images of individuals' health care directives.
- Web accessible system to review and retrieve documents and generate registry report
- Advanced Internet Access for Health Care Facilities with administration console.
- System Support and Administration
- Data Storage and Backup
- Customized Reports

<u>Documents, Letters, Forms and Envelopes including:</u>

- Registration Agreement
- Health Care Directive Templates
- System User Guide
- Registrant enrollment package includes:
    i. Welcome Letter
    ii. Peel-off Wallet Cards
    iii. Peel-off ID stickers for insurance cards and drivers license
- Annual Update Letters

- Community Outreach program including presentation templates, press release templates, meeting agendas, sample invitations and signage templates, health care directive presentation.

Support and Training

- Training for State Staff
- Training for Health Care Facilities and other Organizations Requiring Direct Access
- 7 x 24 system and document retrieval support

Full Service Support Staff and Infrastructure supporting

- Document Scanning and Loading
- Enrollment Fulfillment
- Annual Update
- Registrant Customer Support
- Reporting
- Health Care Provider Support
- System Administration and Maintenance

e. Identify contingency plans for addressing public needs in the event that all or some of the project is not completed according to projected schedule.

Based on our experience with launching other state registries, we do not anticipate any problems that would significantly delay the project launch date. However, because the system is already actively functioning, documents could be registered through the U.S. Living Will Registry® and accessed through the USLWR web pages on a temporary basis until the Virginia web pages are completed.

f. Propose allocation of risk and liability for work completed beyond the agreement's completion date, and assurances for timely completion of the project.

The responsibilities of each party are clearly delineated in the Project Schedule table. We assume responsibility for all aspects of the project for which we are listed as the "Task Owner" on that table. We will do our best to work with the Commonwealth to make sure they stay on schedule with their assigned tasks. Based on our experience in working with other states, we are confident that the project can be completed within the scheduled timeframe.

g. State assumptions related to ownership, legal liability, law enforcement and operation of the project and the existence of any restrictions on the public entity's use of the project.

The U.S. Living Will Registry® will maintain ownership of the proprietary software and patent-protected business methods currently in use. The Commonwealth of Virginia will maintain ownership of the data, and can receive a copy of all data upon sufficient notification. Data can be provided on a variety of media, and there is only a nominal fee to cover our costs in performing the transfer or copy of the data.

h. Provide information relative to phased or partial openings of the proposed project prior to completion of the entire work.

Marketing of the project is a critical aspect for success. Informing health care providers and the public about the registry well in advance of the launch date will lead to a smooth launch. One way to start is to get the Department of Health-hosted web page up and running as soon as possible. This gives stakeholders and the public a place to go for information, and makes the project "real" at an early stage. Other marketing techniques, such as Public Service Announcements (PSA), and notices at state offices and medical venues also helps. We can provide a 30 second PSA that is delivered to you ready for airing as part of our marketing package. This is a separate service that is offered for an additional charge. Please see the Sample PSA disc included.

i. List any other assumptions relied on for the project to be successful.

One of the many benefits of a straightforward, focused registry is that it is not subject to compatibility issues that can plague more complicated systems, such as electronic medical records systems. As a web-based application, the system proposed, and currently in operation across the country, performs a specific function—advance directive and organ donation document storage and retrieval--without attempting to "do it all". Other systems that try to incorporate an entire medical record into the project can get bogged down in their own complexity and are subject to compatibility issues with various hospital and health system-specific software applications. We have no such issues, and can therefore safely assume that our system will function reliably throughout the Commonwealth.

j. List any contingencies that must occur for the project to be successful.

The Commonwealth must commit sufficient funding to complete the project and maintain it into the future.

3. Project Financing

a. Provide a preliminary estimate and estimating methodology of the cost of the work by phase, segment, or both.

Please see Exhibit C for the Cost Proposal.

b. Submit a plan for the development, financing and operation of the project showing the anticipated schedule on which funds will be required. Describe the anticipated costs of and proposed sources and uses for such funds, including any anticipated debt service costs. The operational plan should include appropriate staffing levels and associated costs. Include any supporting due diligence studies, analyses or reports.

The payment schedule is listed at the end of Exhibit C- Cost Proposal. We do not foresee the need to increase staffing or to incur any debt to complete this project.

c. Identify the proposed risk factors and methods for dealing with these factors.

The main risk factor is the ability of the Department of Health to maintain sufficient funding to develop, launch, market and maintain the service over the long term.

d. Identify any local, state or federal resources that the proposer contemplates requesting for the project. Describe the total commitment, if any, expected from governmental sources and the timing of any anticipated commitment. Such disclosure should include any direct or indirect guarantees or pledges of the Commonwealth's credit or revenue.

We do not anticipate requesting any resources from local, state or federal governments, other than the pricing listed above.

4. Additional information as may seem prudent

The U.S. Living Will Registry® owns a registered patent (US 7,213,016 B1) on a process that was developed to allow hospitals the ability to manage all of their advance directives in a central, easily accessible location. This process, called the Living Vault®, enables registration of documents that hospitals are already storing in their record rooms. While the usual registration process requires the registrant to sign a registration agreement, authorizing release of their document, the Living Vault® process allows documents already in the hospital's possession to be registered while maintaining the same privacy status they held as part of the medical record room.

a. Describe the potential value added utility of your proposal.

The existing functionality of the U.S. Living Will Registry® system can fully support the Commonwealth of Virginia's requirements detailed above. The U.S. Living Will Registry® application is a secure database enabling health care providers, hospices, residential care facilities and other authorized parties to access the advance directive document images (tamper proof, read only PDF files) all individuals electronically stored online at the registry's secure data center. The U.S. Living Will Registry® has been operating the database, fulfillment and support processes specified in the Commonwealth of Virginia requirements for more than thirteen years, and have already successfully launched and managed three state registries. We have the experience and the secure, time-tested, reliable and flexible systems in place to establish the Virginia registry quickly and inexpensively.